

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND
IRBESARTAN PRODUCTS LIABILITY
LITIGATION

This relates to: All Actions

No. 1:19-md-2875-RBK
Hon. Robert Kugler

**Plaintiffs' Memorandum of Law in
Opposition to Defendants' Motion to
Exclude Opinions of Philip Russ**

Redacted Version

**PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO
DEFENDANTS' MOTION TO EXCLUDE OPINIONS OF PHILIP RUSS**

On the Brief:
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I. INTRODUCTION

Philip Russ is a pharmaceutical quality compliance professional with nearly thirty years of directly relevant industry experience. He reviewed dozens of deposition transcripts and hundreds of records in this case, using the same generally accepted methodology he applies in his ordinary-course professional work, to reliably opine that [REDACTED]

[REDACTED] The same methodology Mr. Russ applies here was found to be reliable by another court in this Circuit in a litigation that also involved worthless, adulterated drugs due to significant cGMP violations.¹

Defendants do not challenge Mr. Russ's considerable qualifications. They merely nibble around his opinions with weight- and credibility-based attacks. But Defendants' quibbles with Mr. Russ's conclusions, or about which documents are qualitatively more 'important' than others, do not implicate the admissibility of his opinions.

Defendants' first attack—that [REDACTED]

[REDACTED]—is untrue. Both in his report and at his deposition, Mr. Russ explained [REDACTED]

¹ See *Blue Cross Blue Shield Ass'n v. GlaxoSmithKline LLC*, No. 13-4663, 2019 WL 4751883 (E.D. Pa. Sept. 30, 2019) ("BCBS").

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] not a proper basis for a *Daubert* challenge.

Defendants' adjacent attack—that [REDACTED]

Torrent's contention that Mr. Russ intends to [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] 2

Finally, Mr. Russ is not affirmatively opining about ZHP's quality or other systems. He only opines about Teva's and Torrent's cGMP deviations. In that context, he rightly observes that Teva's and Torrent's finished-dose valsartan products were [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] See, e.g., Ex. A (Russ Rpt.) at ¶¶ 53-54, 103.

Defendants' *Daubert* motion as to Mr. Russ should be denied in its entirety.

II. APPLICABLE LEGAL STANDARD

"Under the Federal Rules of Evidence, a trial judge acts as a 'gatekeeper' to

² Ex. A (Russ Rpt.) at ¶ 106 (quoting TORRENT-MDL2875-00005763).

³ Ex. C ([REDACTED])

ensure that ‘any and all expert testimony or evidence is not only relevant, but also reliable.’” *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (citation omitted). Rule 702, the rule that governs expert testimony, has a “liberal policy of admissibility.” *Id.* In essence, the expert testimony must meet the following requirements: “(1) the proffered witness must be an expert, i.e., must be qualified; (2) the expert must testify about matters requiring scientific, technical or specialized knowledge; and (3) the expert’s testimony must assist the trier of fact.” *Id.* at 244.

A. Qualifications

The qualification requirement of Rule 702 is “liberally construed” and satisfied if an expert “possesses specialized expertise.” *Geiss v. Target Corp.*, 2013 WL 4675377, at *4 (D.N.J. Aug. 30, 2013) (citing *Pineda*, 520 F.3d at 244). “At a minimum, a proffered expert witness ... must possess skill or knowledge greater than the average layman....” *Aloe Coal Co. v. Clark Equip. Co.*, 816 F.2d 110, 114 (3d Cir.1987).⁴

B. Reliability

The second Rule 702 requirement (also known as reliability) is taken to “mean[] that the expert’s opinion must be based on the ‘methods and procedures of

⁴ See *Waldorf v. Shuta*, 142 F.3d 601, 627 (3d Cir. 1998) wherein the Third Circuit adopted a broad view regarding expert qualifications in finding that a social worker with qualifications that are “a little thin” could serve as a vocational expert, since he had substantially more knowledge than an average layperson regarding employment opportunities for disabled individuals.

science’ rather than on ‘subjective belief or unsupported speculation.’” *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994) (citation omitted). While such “good grounds” for an expert’s opinion are required, “[t]he grounds for the expert’s opinion merely have to be good, they do not have to be perfect.” *Id.* at 744. Good grounds may exist even if the court believes there “are better grounds for some alternative conclusion” or that “a scientist’s methodology has some flaws such that if they had been corrected, the scientist would have reached a different result.” *Id.* at 744.

Moreover, proponents of expert testimony do not have to “demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are *correct*, they only have to demonstrate by a preponderance of evidence that their opinions are reliable.” *In re DVI, Inc. Sec. Litig.*, No. 03-5336, 2014 WL 4634301, at *5 (E.D. Pa. Sep. 16, 2014) (internal quotation marks omitted) (emphasis original); see also *In re Paoli*, 35 F.3d at 744 (“evidentiary requirement of reliability is lower than the merits standard of correctness”). Scientific study is not the only basis for an expert’s reliability, which may also be founded upon experience. As the Supreme Court later added in *Kumho Tire*, the objective of *Daubert* “is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co. v.*

Carmichael, 526 U.S. 137, 152 (1999). Indeed, the *Daubert* test “may be more flexibly applied in cases where the expert testimony is based on experience.” *In re Front Loading Washing Mach. Class Action Litig.*, 2013 WL 3466821, at *2 (D.N.J. July 10, 2013). Moreover, in the case of experience-based opinions, the fact that an expert has been determined to be qualified weighs in favor of the reliability of her report. *Altieri v. State Farm Fire & Cas. Co.*, No. 09-2342, 2011 WL 1883054, at *3 (E.D. Pa. May 17, 2011).

C. Relevance

The third requirement of Rule 702, known as relevance, is satisfied “if an opinion fits a particular case (and thus helps the trier of fact)” – i.e., there must be a “connection between the scientific research or test result to be presented and particular disputed factual issues in the case.” *Geiss*, 2013 WL 4675377, at *5 (internal quotation marks omitted).

III. BACKGROUND ON MR. RUSS’S EXPERT REPORT

A. Mr. Russ’s Qualifications

Mr. Russ holds a B.S. in chemistry and is the owner and president of Innovative Consultants GXP, which “[REDACTED]
[REDACTED]
[REDACTED].” Ex. A (Russ Rpt.) at ¶4. He has over twenty-seven years of experience in the [REDACTED]

[REDACTED]

[REDACTED]. *Id.* ¶¶ 4-5.

Among his clients are some of the largest pharmaceutical companies in the world. *Id.* at Ex. A thereto (Mr. Russ's CV). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *Id.*

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] This includes the *BCBS* case (in which his expert opinions were admitted), in which he opined (as he opines here) that cGMP failures in quality oversight and manufacturing resulted in inadequate assurances that the products conformed to their represented properties. 2019 WL 4751883, at *1.

B. Mr. Russ's Opinions and Methodology

Mr. Russ's assignment was to [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED] Ex. A at ¶ 1. He principally opines that [REDACTED]

[REDACTED] *Id.*

¶ 2.

Specifically, Mr. Russ [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]" *Id.* ¶ 2. Because of [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]" *Id.*

After discussing his background and experience (*see* Ex. A at ¶¶ 3-11), Mr. Russ first provides [REDACTED] (*id.* at ¶¶ 12-31),

[REDACTED] (*id.* at ¶¶ 32-36), and [REDACTED] (*id.* at ¶¶ 37-45). He next describes [REDACTED]

Id. ¶¶ 46-56. [REDACTED]

In analyzing Teva's and Torrent's [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

The image consists of a series of horizontal black bars of varying lengths, arranged vertically. The bars are solid black and have thin white borders. They are positioned against a plain white background. The lengths of the bars decrease as they move from top to bottom.

5 Teva was using

The image consists of a vertical column of horizontal black bars. These bars are evenly spaced and extend across most of the page's width. They are used to redact sensitive information from a document. The top bar is positioned near the top edge of the frame, and the bottom bar is near the bottom edge. There are approximately 15 such bars visible.

IV. ARGUMENT

A. Mr. Russ Is Qualified and His Opinions Fit the Facts of This Case

Defendants neither dispute Mr. Russ's qualifications, nor challenge the fit/relevance of his opinions. Thus, the sole Rule 702 lane for Defendants' *Daubert* challenges is reliability. As discussed below, Mr. Russ's opinions are the product of reliable methods, reliably applied to the facts of this case.

B. Another Court in This Circuit Has Already Found Mr. Russ's Opinions Reliable in a Case Nearly Identical to This One

Defendants completely ignore the highly pertinent fact that another court in this circuit has already analyzed Mr. Russ's qualifications and methodology (the same one he employs here); found him to be qualified; found his methodology reliable; and found, thusly, his opinions admissible. *Blue Cross Blue Shield Ass'n v. GlaxoSmithKline LLC*, No. CV 13-4663, 2019 WL 4751883, at *8-9 (E.D. Pa. Sept. 30, 2019 ("BCBS")). This Court favorably cited *BCBS* in denying Defendants' motion to exclude Plaintiffs' class damages expert, Dr. Rena Conti, who was another expert in the *BCBS* case and who, like Mr. Russ, also was found by the *BCBS* court to be qualified and whose opinions were reliable. *Id.*; see 2/8/23 Op. (ECF 2261) at 88-89 (citing *BCBS* favorably in denying Defendants' *Daubert* challenge to Dr. Conti at class certification).

In *BCBS*, thirty-eight different TPPs sought to recoup their reimbursements

for drugs that were adulterated due to cGMP failures. *Id.* at *1. The *BCBS* plaintiffs, as with class plaintiffs here, argued that the adulterated drugs were economically worthless and they would not (and could not) have been purchased had the manufacturer disclosed the cGMP deficiencies and adulteration. *Id.*

In support of their claims, the *BCBS* plaintiffs relied on Mr. Russ to show that the defendants “had significant fundamental failures in all six quality systems—which relate to a manufacturer’s ability to certify a drug’s purity, uniformity, quality, and manufacturing.” 2019 WL 4751883, at *4. He ultimately concluded, based on a review of cGMP and other records, that the products manufactured by the defendants “were materially non-compliant with cGMPs and lacked the assurance of conformance to their represented properties.” *Id.* at *1.

The *BCBS* defendants sought to exclude Mr. Russ’s opinions for many of the same reasons Defendants argue here. For instance, the *BCBS* defendants argued that Mr. Russ’s opinions were overbroad, not sufficiently tethered to the facts, and he could not explain at deposition certain things such as why the FDA seized some but not all drugs at the defendants’ manufacturing plant. *Id.* Judge Sánchez thoughtfully analyzed and rejected each challenge, *see id.* at *4-5, and ultimately found that the defendant’s critiques went to credibility, not admissibility, *id.* at *5.

Whereas Defendants previously [REDACTED]

[REDACTED]

D.E. 2040-1 at 8 (Defs.' Mtn. to Preclude Dr. Conti), this time Defendants do not even mention (let alone try to distinguish) Judge Sánchez's *BCBS* opinion. This Court rightfully should be guided by its own analysis and by that which preceded it in *BCBS*.

C. Mr. Russ's Opinions Are Reliable and Reliably Applied to the Facts of This Case

As Mr. Russ explains in his report,



Ex. A at ¶ 50. He continues,



Id. ¶ 51. [REDACTED]



The image consists of a series of horizontal black bars of varying lengths, arranged vertically. The bars are of different widths, with some being relatively short and others being much longer, creating a pattern of horizontal stripes. This visual effect is often used to represent redacted text or to create a specific aesthetic in document layout.

Term	Percentage
Climate change	~95%
Global warming	~95%
Green energy	~85%
Sustainable development	~80%
Circular economy	~75%
Environmental protection	~70%

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The image consists of a series of horizontal black bars of varying lengths, arranged vertically. The bars are solid black and have thin white borders. The lengths of the bars decrease from top to bottom. There are small gaps between the bars.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Mr. Russ also relies on ample evidence that [REDACTED]

[REDACTED]

As Mr. Russ testified:

Ex. B at 190:2-10. The record not only shows that

Mr. Russ elaborated:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Ex. B at 133:18 – 135:11.

Defendants attempt to sidestep the foregoing evidence on which Mr. Russ appropriately bases his opinions. They claim his opinions are unreliable because

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

21 [REDACTED]

[REDACTED]

[REDACTED]

Torrent's accusations fare no better. It claims Mr. Russ

The image consists of eleven horizontal black bars arranged vertically. The bars decrease in length from top to bottom. The top bar is the longest, followed by a shorter bar, then a very long bar, then a medium-length bar, then two short bars, then three medium-length bars, then a long bar, then a medium-length bar, and finally a very long bar at the bottom.

Regardless, Defendants’ arguments “reflect[] a fundamental confusion about the role of the court as a gatekeeper, under *Daubert*, to determine the admissibility of evidence, and the role of the jury, as a fact finder, to determine the weight to be accorded to admitted evidence.” *In re Suboxone (Buprenorphine Hydrochloride & Naxalone) Antitrust Litig*, 13-MD-2445, 2020 WL 6887885, at *30-31 (E.D. Pa. Nov. 24, 2020) (internal quotation marks and citation omitted). Assertions that an opposing expert did not rely on the ‘right’ evidence or ‘better’ evidence do not implicate reliability. *See, e.g., id.* (denying *Daubert* challenge arguing expert

“simply ignored contrary evidence”); *In re J&J Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Liab. Litig.*, 509 F. Supp.3d 116, 194-95 (D.N.J. 2020) (denying *Daubert* challenge to expert who allegedly ignored one study). “Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 596 (1993). Defendants’ criticisms of Mr. Russ are classic fodder for cross-examination. They do not warrant exclusion under *Daubert*.

D. Mr. Russ Is Not Opining on Torrent’s State of Mind

The Court should reject Torrent’s perfunctory attempt to gin-up a state-of-mind attack on Mr. Russ’s opinion regarding [REDACTED]
[REDACTED].

He is not opining on what Torrent thought or knew. Rather, [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

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E. Mr. Russ's Opinion Accurately Recounts That the FDA Explicitly Found ZHP's Valsartan API Was Adulterated

Mr. Russ opines that Teva's and Torrent's VCDs were deficient for two reasons. First, [REDACTED] . Ex. A at ¶¶ 1-2. Second, [REDACTED]

Term	Percentage
GMOs	~95%
Organic	~90%
Natural	~85%
Artificial	~75%
Organic	~70%
Natural	~65%
Artificial	~60%
Organic	~55%
Natural	~50%
Artificial	~45%

Ex. A at ¶ 2 (highlighting added).

Far from this being

Ex. C (highlighting added).

[REDACTED]. Courts routinely permit experts, including Mr. Russ himself, to testify whether cGMP violations exist and the impact that would have. *See, e.g., BCBS*, 2019 WL 4751883, at *4 (permitting Mr. Russ to testify that, due to these chronic [cGMP] failures, GSK could not assure the At-Issue Drugs “conformed to their represented properties of safety, identity, strength, purity, and quality.”) (internal quotation marks omitted); *In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, No. 09-2100, 2011 WL 6302287, at *25 (S.D. Ill. Dec. 16, 2011) (“To the extent [the expert] does offer

²³ [REDACTED]

legal conclusions, the Court finds that [the expert's] testimony is permissible because of the complex nature of the process and procedures and the jury needs assistance understanding it. [The expert's] testimony will assist the trier of fact in understanding the federal regulations, and the jury will be instructed that that the Court, not [the expert] nor any other witness, will instruct the jury on the law in this case."); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 191 (S.D.N.Y. 2009) (denying motion to preclude expert from "testifying about general FDA regulatory requirements and procedures or offering an opinion as to [the pharmaceutical company's] compliance therewith"); *Pfizer v. Teva Pharms. USA, Inc.*, 461 F. Supp. 2d 271, 278–79 (D.N.J. 2006) (finding admissible expert testimony regarding FDA regulation of labeling, advertising, and promotion of prescription drugs, and to what extent firm complied with those requirements).



V. Conclusion

For the foregoing reasons, Defendants' *Daubert* motion to exclude Mr. Russ's opinions should be denied.

Respectfully,

ON BEHALF OF PLAINTIFFS

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Dated: April 11, 2023

CERTIFICATE OF SERVICE

I hereby certify that on this 11th day of April 2023, I caused a true and correct copy of the foregoing to be filed and served upon all counsel of record by operation of the Court's CM/ECF system. In addition, I certify that unredacted versions of the foregoing will be served contemporaneously upon liaison counsel for Defendants as well as the Court.

/s/ David J. Stanoch

David J. Stanoch